K140281

JUL 24 2014

510(k) Summary

In response to the Safe Medical Devices Act of 1990 and as required by 21 CFR 807.87, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based for the Flexi-Lume 510(K) premarket notification.

Owner/Operator: Epic Medical Concepts & Innovations
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Date of Submission: 25 April 2014

Trade Name: Flexi-Lume LED System

Common Name: Flexi-Lume

Classification: 21 CFR 872.7060 Class II Activator, Ultraviolet, for Polymerization

Product code: EBZ

Predicate Device: K121093: D1 LED Curing Light

Device Description: The Flexi-Lume LED System is classified as an Ultraviolet Activator for Polymerization (21 CFR 872.6070) because it is a device intended for the photo-polymerization of light-cured dental materials. The Flexi-Lume contains a multi-function LED that directs light via a fiber optic gooseneck to the patient's mouth. The LED light has several modes: Daylight white (color temperature 5500K), Fluorescent white (color temperature 3500K), Transdental Illumination, Bleaching Light, Non-Curing light (all visible wavelengths excluding blue wavelengths), and Curing Light. The Curing Light mode produces visible blue light in the 430-490nm waveband of the light spectrum with a power density of 1,500mW/cm^2. This power density is sufficient for the product intended uses, generally the photo-polymerization of visible light cured dental materials, restorative composite materials, orthodontic brackets and orthodontic bonding and sealing materials.

The different lighting modes can be selected with touch controls on the housing. The touch controls also include a dimmer which allows the selection of light intensity in all modes except Curing and Bleaching, which have pre-set intensity levels.

The Flexi-Lume runs on 12VDC, powered by a certified AC/DC adapter that can be hidden inside the dental chair.

Indication for Use: The Flexi-Lume LED System is intended to polymerize dental materials, restorative composite materials, orthodontic brackets bonding and sealing materials that are photo-polymerized in the 430~490nm waveband of visible light. It is also intended to illuminate the patient's oral structures. It is also intended for bleaching procedures to apply light to a tooth after it is treated with a bleaching agent.

Discussion of Nonclinical Tests Performed for Determination of Substantial Equivalence: To establish substantial equivalence to the predicate, testing was conducted in accordance with IEC 60601-1. Software validation was performed in accordance with IEC 62304.
Non-clinical bench testing included (in accordance with FDA Guidance Document 1591):

- Verification of Spectral Irradiance Output "Exitance"
- Verification of Irradiance Intensity (at peak wavelength)
- Depth of Cure
- Verification of Case Temperature Rise

Substantial similarities to predicate

Description	Submission Device (Device Name)	Predicate Device (Device Name & K#)
Intended use	The Flexi-Lume LED System is intended to polymerize resinous dental materials, restorative composite materials, orthodontic brackets bonding and sealing materials that are photo-polymerized in the 430~490nm waveband of visible light.	Same
Device Design	- Light source is an **LED** - Powered by standard AC 120V power - Light emitter tip can be removed and sterilized	- Light source is an **LED** - Powered by Standard AC 120V power - Light emitter tip can be removed

		and sterilized
Curing Light Intensity	1,500 mW/cm^2	1,500 mW/cm^2
Curing Depth	At least 2.5mm	At least 2.5mm
Curing Light Wavelength	430-490nm (460 peak)	430-490nm
FDA recognized standards followed	IEC 60601-1, ISO 10993, IEC 62304, ANSI/ADA Specification No. 48	IEC 60601-1, ISO 10993

Conclusion: The Flexi-Lume is substantially similar to the predicate in intended use, operation, and function. It is substantially equivalent to the predicate in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2014

Epic Medical Concepts & Innovations
Mr. Alex Waller
Director of Engineering
6950 Squibb Road, Suite 300
Mission, KS 66202

Re: K140281
Trade/Device Name: Flexi-Lume LED System
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Codes: EBZ, EEG, EAY
Dated: April 25, 2014
Received: April 28, 2014

Dear Mr. Waller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140281

Device Name: Flexi-Lume LED System

Indications for Use: The Flexi-Lume LED System is intended to polymerize dental materials, restorative composite materials, orthodontic brackets bonding and sealing materials that are photo-polymerized in the 430~490nm waveband of visible light. It is also intended to illuminate the patient's oral structures. It is also intended for bleaching procedures to apply light to a tooth after it is treated with a bleaching agent.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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